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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) IB-1627	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 (37 CFR 1.8(a)) For transmission to 571-273-8300 on <u>March 5, 2007</u> Signature <u>R'Sue P. Caron</u> Typed or printed name <u>R'Sue P. Caron</u>		Application Number <u>09/845,597</u>	Filed <u>Apr. 30, 2001</u>
		First Named Inventor <u>Tomsia</u>	
		Art Unit <u>1771</u>	Examiner <u>Sperty</u>
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>52,699</u> <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
		<u>R'Sue P. Caron</u> Signature <u>R'Sue Popowich Caron</u> Typed or printed name <u>510-486-6503</u> Telephone number <u>3/5/07</u> Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> Total of <u>1</u> forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 123 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Docket No. IB-1627

MAR 05 2007 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Tomsia
Appl. No. : 09/845,597
Filed : April 30, 2001
For : GLASS/CERAMIC COATINGS FOR IMPLANTS
Examiner : Sperty
Group Art Unit: 1771

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
Mail Stop AF
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

Applicants received a Final Office Action, dated September 27, 2006, rejecting all pending claims, 1, 3, 5, 8-12, 20-28, 30 in the patent application ('597) indicated above. Because Applicants' priority claim to 60/201,556 ('566), filed May 1, 2000, has been denied, the Examiner views publications from February 2000 and June 1999 as prior art to the instant invention. The publications and rejections are as follows:

- (1) "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published February 2000.
- (2) "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published February 2000
- (3) "A multilayer approach to fabricate bioactive glass coatings on Ti alloys," by Gomez-Vega et al, published June 1999.

Claims 1, 3, 5, 8-12 and 20-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by (1).

Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over (2) and further in view of (3).

Applicants respectfully request review of the Examiner's denial of the priority claim to provisional patent application 60/201,556.

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Examiner's Denial of Priority Claim

The Examiner has denied Applicant's claim for priority to Provisional Application 60/201,556. The reasons given are:

1. The specification of the provisional application does not meet the requirements of a "specification" according to 37 CFR 1.77 (b) and (c), which necessitates a certain format and subject matter for a specification. The present collection of previously published articles, including ones not even written by the inventors, does not comply with 37 CFR 1.77 (b) and (c). Therefore, priority to said provisional application is denied.
2. The IDS designates three articles as Prior Art which are also included as part of the "Provisional Application."
3. The provisional application contains a collection of articles which are not seen to provide support for the claimed invention.

Applicants' Arguments as to Priority Claim

Applicants address the Examiner's reasons for denial of priority claim by number below:

Reason 1

A provisional application need not meet the requirements of a "specification" according to 37 CFR 1.77 (b) and (c), as these sections refer to a regular *utility* application. The requirements for a provisional application are given by 37 CFR 1.51 (c), which states:

(c) A complete provisional application filed under § 1.53(c) comprises:

- (1) A cover sheet identifying:
 - (i) The application as a provisional application,
 - (ii) The name or names of the inventor or inventors, (see § 1.41(a)(2)),
 - (iii) The residence of each named inventor,
 - (iv) The title of the invention,
 - (v) The name and registration number of the attorney or agent (if applicable),
 - (vi) The docket number used by the person filing the application to identify the application (if applicable),
 - (vii) The correspondence address, and
 - (viii) The name of the U.S. Government agency and Government contract number (if the invention was made by an agency of the U.S. Government or under a contract with an agency of the U.S. Government);
- (2) A specification as prescribed by the first paragraph of 35 U.S.C. 112, see § 1.71;
- (3) Drawings, when necessary, see §§ 1.81 to 1.85; and
- (4) The prescribed filing fee and application size fee, see § 1.16.

The first paragraph of 35 U.S.C. 112 states:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The Examiner states that some of the articles contained in the '566 were not written by the inventors. This is not a requirement under 37 CFR 1.51 (c). (Among the articles in the provisional application are two that were written not by but *about* the inventors and their new, novel bioactive glasses.)

Applicants respectfully submit that the provisional application, as filed, meets the criteria for a provisional application as stated in 37 CFR 1.51 (c).

Reason 2

The articles contained within '566 are listed also in the IDS for the non-provisional application. The Examiner is mistaken when she states that the IDS designates the articles as "Prior Art".

The following is quoted from the MPEP §2129 IV:

Mere listing of a reference in an information disclosure statement is not taken as an admission that the reference is prior art against the claims. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354-55, 66 USPQ2d 1331, 1337-38 (Fed Cir. 2003) ...

The listing in the IDS of articles included in the provisional application does not constitute a statement by the Applicants that the articles are prior art.

Reason 3

The Examiner states that '566 does not provide support for the claimed invention. Applicants respectfully disagree. The pending independent claims (Claims 1 and 20) in '597 are listed below with references to '566 which provide support for the claims.

Independent Claim 1 recites a multilayer article comprising a metal substrate and a first layer comprising a glass composition which comprises, 44.2 to 67.7 wt% SiO₂, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na₂O, 2.2 to 6.5 wt% K₂O and 6.0 wt% P₂O₅, wherein the glass composition contains hydroxyapatite particles in an amount of up to 50 wt%. Support for Claim 1 is indicated in the following Table:

Claim 1	Provisional 60/201,556 ('566)
1. A multilayer article comprising,	
a metal substrate,	Page 2, col 2, 4 th full ¶
a first layer comprising an inner and outer	Page 2, col 2, 4 th full ¶

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surface, said first layer comprising a glass composition,	
said glass composition comprising, 44.2 to 67.7 wt% SiO ₂ , 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na ₂ O, 2.2 to 6.5 wt% K ₂ O and 6.0 wt% P ₂ O ₅ ,	Page 2, col 2, 1 st full ¶ Page 2, Table I
wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.	Page 2, col 2, 4 th full ¶ Page 8, col 1 lines 8-9 Page 14, Table II

Independent Claim 20 recites multilayer article comprising a substrate that is Ti or Ti₆Al₄V, a first layer and n intermediate layers disposed between the first layer and the substrate. The first layer and the n intermediate layers each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles in an amount up to 50 wt%. The glass composition comprises about 44.2 to about 67.7 wt% SiO₂, about 10.1 to about 23.4 wt% CaO, about 5.7 to about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na₂O, about 2.2 to about 6.5 wt% K₂O and about 6.0 wt% P₂O₅. Support for Claim 20 is indicated in the following Table:

Independent Claim 20	Provisional 60/201,556 ('566)
20. A multilayer article comprising,	
a metal substrate comprising Ti or Ti ₆ Al ₄ V,	Page 2, line 5 Page 18, col 1, 1 st ¶
n intermediate layers, where n is an integer,	Page 2, col 2, 4 th full ¶
a first layer comprising an inner and outer surface,	
said n intermediate layers disposed between the metal substrate and the first layer,	Page 2, col 2, 4 th full ¶
wherein the n intermediate layers and the first layer each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles (HA),	Page 2, col 2, 4 th full ¶
said glass composition comprising, about 44.2 to about 67.7 wt% SiO ₂ , about 10.1 to about 23.4 wt% CaO, about 5.7 to about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na ₂ O, about 2.2 to about 6.5 wt% K ₂ O and about 6.0 wt% P ₂ O ₅ ,	Page 2, col 2, 1 st full ¶ Page 2, Table I
and wherein said hydroxyapatite particles being present in the glass/hydroxyapatite admixture in an amount of up to 50 wt%.	Page 2, col 2, 4 th full ¶ Page 8, col 1 lines 8-9 Page 14, Table II

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CONCLUSION

In view of the foregoing arguments, Applicants respectfully request that the denial of priority to application 60/201,556 be rescinded. Applicants submit that the application 09/845,597 is entitled to claim priority to provisional patent application 60/201,556.

Upon finding that the priority claim to provisional patent application 60/201,556 is proper, Applicants respectfully submit that the application is in condition for allowance.

Please charge any fees due, including fees for extensions of time, to Deposit Account No. 120690.

Respectfully submitted,
The Regents of the University of California
Customer No. 08076

Date: March 5, 2007

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